

AMENDMENTS TO THE CLAIMS

The following is a complete, marked up listing of revised claims with a status identifier in parentheses, underlined text indicating insertions, and strikethrough and/or double brackets indicating deletions.

Listing of the Claims

1.-9. (CANCELLED)

10. (CURRENTLY AMENDED) A method for producing a drug containing composite particle, comprising:

a primary particle formation step of forming primary particles each of which includes nano particles whose average particle diameter is less than 1000 nm; and

a combining step of combining the primary particles with each other so that the primary particles are reversibly collected, wherein a drug powder is used as the nano particles, ~~or the primary particles.~~

11. (ORIGINAL) The method as set forth in claim 10, wherein each of the primary particles is a nano particle clump obtained by clumping a plurality of the nano particles.

12. (CURRENTLY AMENDED) The method as set forth in claim 10, further comprising a nano particle formation step of forming the nano particles ~~in accordance with~~ by spherical crystallization.

13. (CURRENTLY AMENDED) The method as set forth in claim 10, wherein, in the combining step, the primary particles are subjected to secondary granulation ~~in accordance with~~ a fluid bed dry granulation method.

14. (CURRENTLY-AMENDED) The method as set forth in claim ~~13~~10, wherein an average particle diameter of the primary particles is within a range of from 0.01 μm or more to 500 μm or less.

15. (CURRENTLY-AMENDED) The method as set forth in claim ~~10~~13, wherein a binder is used to combine the primary particles with each other in the fluid bed dry granulation method.

16. (ORIGINAL) The method as set forth in claim 15, wherein the binder is an aqueous solution of a biocompatible polymer.

17. (CURRENTLY AMENDED) The method as set forth in claim 10, wherein, ~~in the combining step~~ includes adhering, the primary particles ~~are made to adhere to~~ a surface of each ~~of a~~ carrier particle using a dry mechanical particle combining method ~~particles, which are~~ wherein said carrier particle is larger than the primary particles in terms of an external diameter, in accordance with a dry mechanical particle combining method.

18. (CURRENTLY AMENDED) The method as set forth in claim 17, wherein an average particle diameter of the primary particles is within a range of from 0.01 μm or more to 500 μm or less, and an average particle diameter of the carrier particles is within a range of from 1 μm or more to 500 μm or less.

19. (PREVIOUSLY PRESENTED) The method as set forth in claim 17, wherein a polysaccharide powder or a hydrophilic polymer powder is used as the carrier particle.

20. (CURRENTLY AMENDED) The method as set forth in claim 17, further comprising a carrier particle surface modification step of modifying the surface of the carrier particle, ~~in accordance with~~ using the fluid bed dry granulation method or the dry mechanical particle combining method, before carrying out the combining step.

21. (CURRENTLY AMENDED) The method as set forth in claim 20, wherein, in the carrier particle surface modification step, the surface of the carrier particle is smoothed ~~in accordance with~~ the fluid bed dry granulation method or the dry mechanical particle combining method, or the carrier particle is combined with lubricant particles, so as to modify the surface of the carrier particle.

22. (CANCELLED)

23. (CURRENTLY AMENDED) A method for producing a drug containing composite particle, comprising:

making a mixture, containing nano particles whose average particle diameter is less than 1000 nm and a drug powder whose average particle diameter is larger than the average particle diameter of the nano particles, into a composite particle ~~in accordance with~~using a fluid bed dry granulation method or a dry mechanical particle combining method, so as to modify a surface of the drug powder.

24. (ORIGINAL) The method as set forth in claim 23, wherein a lubricant powder is used as the nano particles.

25. (ORIGINAL) The method as set forth in claim 24, wherein a colloidal inorganic compound powder or a surfactant powder is used as the lubricant powder.

26. (ORIGINAL) The method as set forth in claim 25, wherein the colloidal inorganic compound powder is colloidal silica.

27. (ORIGINAL) The method as set forth in claim 25, wherein the surfactant powder is magnesium stearate or sugar ester.

28. (CURRENTLY AMENDED) The method as set forth in ~~claim 23~~claim 24, wherein a polymer nano particle obtained ~~in accordance with~~by spherical crystallization is used as the lubricant powder.

29. (ORIGINAL) The method as set forth in claim 28, wherein the polymer nano particle is constituted of a lactic acid - glycolic acid copolymer or hydroxymethyl cellulose phthalate.

30. (PREVIOUSLY PRESENTED) The method as set forth in claim 23, wherein the average particle diameter of the drug powder is within a range of from 0.01 μm or more and 500 μm or less.

31.-36. (CANCELLED)

37. (CURRENTLY AMENDED) The method as set forth in claim 11, further comprising a nano particle formation step of forming the nano particles ~~in accordance with~~by spherical crystallization.

38. (CURRENTLY AMENDED) The method as set forth in claim 11, wherein, in the combining step, the primary particles are subjected to secondary granulation ~~in accordance with a~~ fluid bed dry granulation method.

39. (CURRENTLY AMENDED) The method as set forth in claim 11, wherein, in the combining step, the primary particles are subjected to secondary granulation in ~~accordance with a~~ fluid bed dry granulation method.

40. (CURRENTLY AMENDED) The method as set forth in claim 11, wherein, ~~in the combining step included adhering, the primary particles are made to adhere to a surface of each of a carrier particle using a dry mechanical particle combining method~~ particles, which are wherein said carrier particle is larger than the primary particles in terms of an external diameter, ~~in accordance with a dry mechanical particle combining method.~~

41. (PREVIOUSLY PRESENTED) The method as set forth in claim 18, wherein a polysaccharide powder or a hydrophilic polymer powder is used as the carrier particle.

42. (CURRENTLY AMENDED) The method as set forth in claim 18, further comprising a carrier particle surface modification step of modifying the surface of the carrier particle, ~~in accordance with~~ using a fluid bed dry granulation method or the dry mechanical particle combining method, before carrying out the combining step.

43.-44. (CANCELLED)

45. (PREVIOUSLY PRESENTED) The method as set forth in claim 24, wherein the average particle diameter of the drug powder is within a range of from 0.01 μm or more and 500 μm or less.

46. (CANCELLED)

47. (NEW) The method as set forth in claim 1, further comprising:
preparing a casing including a cylindrical rotator that has a vertical axis provided at a center of the casing and has a receiving face directing the center, the casing including a press head that has the same vertical axis and directs the receiving face of the cylindrical rotator;
putting the mixture into the casing; and
rotating at least one of the receiving face and the press head around the vertical axis,
wherein, in giving the pressure and the shearing force, the pressure and the shearing force are given to the mixture located at a press section between the press head and the receiving face by rotating at least one of the receiving face and the press head around the vertical axis so as to combine the powder materials with each other.

48. (NEW) The method as set forth in claim 47, wherein a horizontal cross-sectional surface of the press head is semi-circular.

49. (NEW) The method as set forth in claim 48, wherein a curvature of the press head is higher than a curvature of the receiving face.

50. (NEW) The method as set forth in claim 9, further comprising:
preparing a casing including a cylindrical rotator that has a vertical axis provided at a center of the casing and has a receiving face directing the center, the casing including a press head that has the same vertical axis and directs the receiving face of the cylindrical rotator;
putting the mixture into the casing;
rotating at least one of the receiving face and the press head around the vertical axis; and
giving a pressure and a shearing force to the mixture located at a press section between the press head and the receiving face by rotating at least one of the receiving face and the press head around the vertical axis so as to combine the powder materials with each other.

51. (NEW) The method as set forth in claim 50, wherein a horizontal cross-sectional surface of the press head is semi-circular.

52. (NEW) The method as set forth in claim 51, wherein a curvature of the press head is higher than a curvature of the receiving face.

53. (NEW) The method as set forth in claim 10, further comprising:

preparing a casing including a cylindrical rotator that has a vertical axis provided at a center of the casing and has a receiving face directing the center, the casing including a press head that has the same vertical axis and directs the receiving face of the cylindrical rotator;

putting the mixture into the casing;

rotating at least one of the receiving face and the press head around the vertical axis; and

giving a pressure and a shearing force to the mixture located at a press section between the press head and the receiving face by rotating at least one of the receiving face and the press head around the vertical axis so as to combine the powder materials with each other.

54. (NEW) The method as set forth in claim 53, wherein a horizontal cross-sectional surface of the press head is semi-circular.

55. (NEW) The method as set forth in claim 54, wherein a curvature of the press head is higher than a curvature of the receiving face.

56. (NEW) The method as set forth in claim 23, further comprising:

preparing a casing including a cylindrical rotator that has a vertical axis provided at a center of the casing and has a receiving face directing the center, the casing including a press head that has the same vertical axis and directs the receiving face of the cylindrical rotator;

putting the mixture into the casing;

rotating at least one of the receiving face and the press head around the vertical axis; and

giving a pressure and a shearing force to the mixture located at a press section between the press head and the receiving face by rotating at least one of the receiving face and the press head around the vertical axis so as to combine the powder materials with each other.

57. (NEW) The method as set forth in claim 56, wherein a horizontal cross-sectional surface of the press head is semi-circular.

58. (NEW) The method as set forth in claim 57, wherein a curvature of the press head is higher than a curvature of the receiving face.

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